UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)))	MDL NO. 1456 CIVIL ACTION: 01-CV-12257-PBS
	))	(Subcategory Docket: 06-11337)
THIS DOCUMENT RELATES TO *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.*, No. 07-CV-11618-PBS	))))	Judge Patti B. Saris Magistrate Judge Marianne B. Bowler

ABBOTT LABORATORIES INC.'S REPLY IN SUPPORT OF
ITS MOTION FOR SUMMARY JUDGMENT

Dated: December 4, 2009

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Abbott's opening brief showed that Ven-A-Care has raised several discrete claims that are amenable to summary judgment in Abbott's favor. In particular, Ven-A-Care should not be allowed to pursue: (1) claims accruing prior to six years before Ven-A-Care first asserted them in a complaint (because the claims are barred by the statute of limitations); (2) claims that accrued after February 2001 when Ven-A-Care brought its claims about the Abbott Ery drugs (because the claims are barred by the recognized "perfect storm" of information then available to government payors, including specific disclosures regarding spreads on the Ery drugs at issue in this case); (3) Count I, which raises an anti-kickback claim for which Ven-A-Care still can offer no evidence; (4) claims from Texas and California, which have been resolved by a previous settlement; and (5) damages that arise from Medicaid payments that were not based on a reported price for an Ery drug or from plaintiff's expert's impermissible "extrapolations." Paring away these groundless claims will bring focus to this case and leave the Court with a much more manageable trial.

Unable to contest most of Abbott's statements of fact (*see* Abbott's SOF Reply), Ven-A-Care offers a number of legally and factually flawed arguments in an attempt to fend off summary judgment. As discussed below, each argument fails.

I. THE STATUTE OF LIMITATIONS BARS CLAIMS ACCRUING MORE THAN SIX YEARS BEFORE THEY WERE MADE, AND VEN-A-CARE'S NEWLY ADDED CLAIMS DO NOT RELATE BACK TO EARLIER COMPLAINTS.

There is no dispute that Ven-A-Care's original 2001 complaint against Abbott focused exclusively on Abbott's published WACs and named only six Ery products (comprised of 13 NDCs). Through a series of amendments, Ven-A-Care expanded its action greatly: adding claims based on Direct Price and AWP in 2002 and 2005 respectively; piling on claims relating to eleven additional Ery products (comprised of 30 more NDCs) in 2005 and 2007; and in the process expanding the case from eight to forty-nine Medicaid programs and, according to Ven-

A-Care's expert, from $2.3 million to $15.5 million of alleged damages. Abbott simply asks that the FCA's six-year statute of limitations be applied to each amendment, which will appropriately narrow the scope and reach of Ven-A-Care's claims. Because Ven-A-Care agrees that the FERA amendment (111 P.L. 21 § 4(b)) provides no relief to Ven-A-Care, which is pursuing this action without government intervention, (VAC Resp. at 10), and there is no other relation-back provision in the FCA, Ven-A-Care turns to relation back under Rule 15(c)(1)(B) and the FCA's tolling provision. Neither permits Ven-A-Care to escape the FCA's six-year statute of limitations and to avoid the just result that Abbott seeks.

A. VAC's Claims Relating To Direct Prices And AWPs, Added In 2002 and 2005 Respectively, Do Not Relate Back To The 2001 Complaint.

Ven-A-Care's first complaint adding claims regarding Abbott's Ery drugs (the First Amended Complaint) was clearly limited to claims relating to the published WACs (sometimes referred to in the complaint as "prices charged to wholesalers") and the impact of those reported prices on the eight state Medicaid programs that allegedly used WACs to calculate payments to pharmacies. (*See, e.g.*, Berlin Ex. 8 ¶¶ 2, 3, 4, 5, 32, 42, 53, 54, 55, 58, 64, 65, 75, 77, 80, 81, 82, 84, 87-88, 92, 96 (comparing "false reported WAC" with "VAC's cost"), 98, 101, 105, 109; *see also* Berlin Ex. 11 (VAC 30(b)(6) Dep.) at 435:7-437:8 (explaining that Ven-A-Care's "original thought process" was to uncover "WAC fraud" and "our reasons for adding [additional allegations] changed over time in our discussions with the attorneys."); VAC Resp at 5-6 (conceding that 2001 complaint focused on WACs).) Ven-A-Care did not add claims relating to Direct Prices or AWPs until it filed its Second and Third Amended Complaint in 2002 and 2005, respectively.

Ven-A-Care concedes that its 2001 Complaint focused on alleged WAC fraud and did not include specific claims for alleged Direct Price or AWP fraud. (VAC Resp. at 5-6.)

Nevertheless, Ven-A-Care proffers three (erroneous) bases that the claims added in 2002 and 2005 relate back to the earlier complaint. First, Ven-a-Care argues that Direct Prices were set "at a level simply 5% greater than the false WACs." This is factually false (Berlin II Ex. 1, 30(b)(6) Fiske Dep. at 112:19-23). Second, Ven-A-Care argues the compendia allegedly derived the AWPs from WACs. This was inconsistent with Abbott's understanding (*id*. at 104:17-105:5.) Third, Ven-A-Care argues that the First Amended Complaint mentioned the pricing terms in passing. That 153-page, 180-paragraph complaint referred to "AWP" or "Direct price" only three times, and then only to note that these are two of the many price terms used in the industry. (Berlin Ex. 8 ¶ 31-32, 38.[1])

Further, finding no independent basis under the FCA or FERA for relation back, Ven-A-Care relies on F.R.C.P. 15(c) (1)(B), which requires that the earlier complaint provide notice of the later claim. *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 498 F. Supp. 2d 389, 398 (D. Mass. 2007) (specifically ruling that notice is required for relation back under Rule 15(c)(2) [now 15(c)(1)(B)]). (*See also* VAC Resp. at 12 (Ven-A-Care agreeing).[2] Merely mentioning price terms in passing in the 2001 complaint is a far cry from bringing claims about Direct Price and AWPs and most certainly did not provide notice to Abbott or the government that Ven-A-Care was pursuing claims other than for WACs.[3] Accepting Ven-A-Care's contrary argument would render Rule 15(c)(1)(B)'s standard for relation back meaningless. Ven-A-Care's late-added Direct Price and AWP claims cannot be construed as arising from the WAC-based claims

[1] Neither term is used in ¶¶ 53, 56, 83, or 84, as Ven-A-Care inaccurately states on page 14 of its response.

[2] Because the FCA provides no independent basis for relation back here Rule 15(c)(1) now 15(c)(1)(A) does not apply, so it is irrelevant whether that provision requires notice.

[3] The use of "Direct Price" and "AWP" in the First Amended Complaint stands in sharp contrast to the Second and Third Amended Complaints, which affirmatively made claims relating to Direct Price reporting and AWPs. (*See, e.g.*, Berlin Ex. 9 ¶¶ 6 (alleging inflated Average Wholesale Price), 141 (Abbott "knowingly defrauded" California Medicaid through its direct prices); Berlin Ex. 10 ¶¶ 3 (alleging "inflated Average Wholesale Price ('AWP')"), 11, 68-71, 145 (referring to AWP spreads), 159, 194 (with charts listing AWPs for Erys).)

alleged in the 2001 First Amended Complaint and cannot relate back.

B. Claims About Additional Ery Drugs Do Not Relate Back To The First Complaint That Named An Ery Drug.

In light of this Court's previous rulings, Abbott does not argue in this motion that different NDCs of the same Ery drug cannot relate back to when the drug was first named in a complaint. Instead, as discussed in Abbott's opening brief (at 18-20), Abbott asks the Court to apply the statute of limitations on a drug-by-drug basis. Ven-A-Care's opposing arguments are easily dispatched.

First, all of Ven-A-Care's arguments about NDCs are irrelevant given that Abbott seeks judgment on a drug-by-drug (not NDC-by-NDC) basis. (VAC Resp. 15-16.) Second, Ven-A-Care's argument that all Ery formulations should be considered one drug because they all derive from "the same core erythromycin salt ingredient" (*id.* at 15) assumes a pharmacologically, medically, and legally invalid view of drugs. These drugs are not treated interchangeably outside the Court; there is no reason to treat them as such in this case. FDA did not approve the different Ery drugs at the same time. (*See* FDA Drug Details, Berlin II Ex. 2.) A doctor cannot prescribe, for example, Ery-Tab® and Pediazole® suspension interchangeably; indeed the different formulations are prescribed for different medical conditions. (Berlin Ex. 31 ¶ 6.) Third, Ven-A-Care's blanket claim of fraud does not obviate the burden of proof as to each drug, and Ven-A-Care cites no law to support such a standard, which would throw the doors open wide for relation back in FCA cases. Ven-A-Care's unsupported and insupportable position is a slippery slope of convenience that would similarly justify treating all of a company's different drugs as one drug, for purposes of avoiding the statute of limitations. No court has adopted such a view, and this Court should not be the first.

Ven-A-Care does not even have a good faith basis for expanding the scope of existing

law-additional drugs were added over the years as Ven-A-Care's attorneys discovered, probably through discovery in other cases, the existence of additional drugs in the Ery family. (Berlin Ex. 11 (VAC 30(b)(6) Dep.) at 437:22-438:8.)

C. The FCA's Tolling Provision Does Not Extend The Statute Of Limitations In This Case.

Ven-A-Care attempts to extend the FCA's six-year statute of limitations by invoking the FCA's tolling provision, which permits suits up to "3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed." 31 U.S.C. § 3731(b)(2). Ven-A-Care spends a page-and-a-half discussing this Court's earlier ruling, on a motion to dismiss, that the tolling provision *can* apply to relators in non-intervened cases, but then presents no facts to show why the tolling provision *should* apply here – *i.e.*, that the facts material to its action were not known or should not reasonably have been known by the United States (or Ven-A-Care).[4] Ven-A-Care does not make this required showing because it cannot.

Ven-A-Care admits that, well before 2001, it had the ability to discover the facts that led to its claims – that the prices at issue were right under Ven-A-Care's nose. (Berlin Ex. 11 (VAC 30(b)(6) Dep.) at 42:2-43:3.) Ven-A-Care's Rule 30(b)(6) witness, John Lockwood, acknowledged that before 2000, "it would have been possible" for Ven-A-Care to discover its claims by reviewing the wholesaler catalogs and other pricing information in its possession. (*Id*.

[4] Abbott respectfully disagrees with the court's recent ruling in the *Actavis* case (subsequent to Abbott's opening summary judgment brief) that the tolling provision can apply to a relator suing without government intervention. *See United States ex rel. Sanders v. North American Bus Indus., Inc.*, 546 F.3d 288, 294 (4th Cir. 2008) *United States ex rel. Sikkenga v. Regence Bluecross Blueshield*, 472 F.3d 702, 723-25 (10th Cir. 2006); *U.S. ex. rel. Told v. Interwest Const. Co.*, 505 F. Supp. 2d 1245, 1248-49 (D. Utah 2007). If the Court is unwilling to reconsider this legal issue in the face of the overwhelming law favoring Abbott's position, Abbott wishes to preserve this issue for an appeal if necessary.

at 36:11-19.) Lockwood testified that "we had the pricing information over a period of time and I think our reasons for adding [the Erys] changed over time in our discussions with the attorneys." (*Id*. at 437:22-438:8.) In addition, as recounted in Abbott's opening brief (at 6-8), the record reveals overwhelming evidence that the public and government payors knew about the very price spreads of which Ven-A-Care complains here. There is simply no room for Ven-A-Care to avail itself of the tolling provision based on the implausible assertion that the underlying facts about AWP spreads and marketing practices were not known in 2001 through 2007. Furthermore, Ven-A-Care's argument does not make sense and cannot be reconciled with its own allegations – Ven-A-Care would have this court believe that Abbott was marketing the Erys' spreads, but so poorly that no one could discover the conduct. The tolling provision provides no relief for Ven-A-Care.

II. GOVERNMENT KNOWLEDGE AND USE OF THE ALLEGED PRICE SPREADS PRECLUDES DAMAGES ACCRUING AFTER FEBRUARY 2001.

Ven-A-Care does not dispute that, by the time that Ven-A-Care filed its complaint in February 2001, the government knew that AWP spreads had grown to over 190% for multi-source drugs generally and to 125-600% for the specific Ery drugs. By that time, the evidence of knowledge is so longstanding and overwhelming – a "perfect storm," as this Court has labeled it – that there can be no genuine issue of material fact that the government was knowingly and purposefully using the spreads. By February 2001, the government knew the following.

- For decades, AWP had been considered a "non-discounted list price," and "[p]harmacies purchase drugs at prices that are discounted significantly below AWP or list price." (Berlin Ex. 12 at 10.193.)
- For decades, it was well known that there were significant average spreads between pharmacies' average acquisition costs and AWPs which grew to 280% for generic drugs with MACs in the late 1990s (SOF ¶¶ 38-39) and increased to 194% for multi-source drugs by 2001. (*Id.* ¶¶ 35-36, 41) There were also widely recognized spreads much larger than these averages. (*Id.* ¶ 27.)

- Spreads for Abbott's Erys were widely reported. *1984* the HHS-OIG reported spreads on Abbott's EES 400® tabs up to 56% (SOF ¶ 25); *1991*, the OIG reported a spread of 124% for Ery-Tab® 250 mg (between prices in Canada and *the HCFA FUL*) (*id.* ¶ 28); *1992*, testimony to Congress reported spread on E.E.S.® 400 tabs, E.E.S.® liquid, Ery-Tab®, Erythrocin® and Pediazole® suspension of 125-632% – equal to or larger than the spreads alleged in VAC's complaints (*id.* ¶ 30; *see also id.* ¶ 31)[5]; *1998* and *1999* Myers & Stauffer reported spreads of 190% on Ery-Tab® and 280% for multi-source drugs that had a MAC price, including Ery-Tab® (*id.* ¶¶ 37, 39).

- In February 2001, VAC filed its first complaint against Abbott alleging fraudulently inflated reported prices for certain Ery drugs. By this time, the government had Ven-A-Care's Section 3730(b)(2) disclosure and the Econolink database, which Ven-a-Care claims supports its allegations and contains all relevant information regarding the alleged spreads. (SOF ¶ 51.)

- From 1994 and throughout the period alleged in the complaint, Abbott was disclosing to the government Abbott's Average Manufacturer's Price on the Erys. (SOF ¶ 79.)[6]

Ven-A-Care cannot, and does not, deny these undisputed facts. (SOF Reply ¶¶ 25-41.) As a result, Ven-A-Care cannot credibly show causation as a matter of law in the face of years of government knowledge about and use of Ery spreads to provide additional profits to pharmacies. (SOF ¶ 21-22.)

[5] Ven-A-Care raises two arguments about these reported spreads. First, Ven-A-Care claims that the Erys listed may not have been Abbott's Erys. Ven-A-Care is wrong because the drugs listed were Abbott trade named Erys. Regardless of Ven-A-Care's nit-picking of the Meditz affidavit (Berlin Ex. 31), these Erys could not have been referring to anything other than the Abbott Erys, and anyone with any knowledge of these drugs would have known that. (Ex. 11 United States Patent and Trademark Office Search Results) Second, Ven-A-Care belabors that the prices submitted by NARD to Congress in 1992 were not available to the NARD pharmacies. Ven-A-Care claims incorrectly that the contract prices were available only to hospitals (*see* VAC SOF Resp. ¶ 20), even though Mr. Rector from NARD testified that the prices were available to "purchasers, *including* hospitals," and referred to "pharmacies." (*See* Anderson Ex. 26(S) at 295-96.) Ven-A-Care even cites a portion of the record where Mr. Rector states that the prices were available to "many other for-profit pharmacies." (Abbott agrees that Mr. Rector indicated that the contract prices were not available to the NARD members; clearly, however, the prices were available to other pharmacies in the market, and Ven-A-Care's inflammatory rhetoric about Abbott attempting to mislead the Court is misplaced. Abbott used a complete copy Mr. Rector's testimony before Congress in many depositions including the Rule 30(b)(6) deposition of Ven-A-Care in this case. (SOF Reply ¶ 29.)) Finally, Ven-A-Care's assertions about Prucare (VAC SOF Resp. ¶ 21) are unsupported and immaterial. Ven-A-Care cites no evidence with respect to Prucare's operations in the early 1990s (and Ven-A-Care attaches none of the cited evidence, in violation of Local Rule 56.1 ("Copies of all referenced documentation shall be filed as exhibits to the motion or opposition.")).

[6] For this motion, the Court need not resolve why spreads existed, why the government thought that they existed or why the government continued to pay the allegedly inflated Medicaid ingredient cost payments, but in fact the reasons are clear. (*See* SOAF ¶¶ 81; 84-86; 94-96; SOF ¶¶ 91-92; 95-96.)

Without a credible direct response, Ven-A-Care instead mislabels Abbott's argument as an "attempt to fault the government for failing to mitigate damages." Abbott is not attempting to impose a duty to mitigate upon the government.[7] Mitigation of damages is the "principle requiring a plaintiff, after an injury or breach of contract, to make reasonable efforts to alleviate the effects of the injury or breach." *Black's Law Dictionary* at 1093 (9th ed. 2009). Abbott is not making this argument.

The argument that Abbott makes is that, by 2001, the government knew about the spreads, and was using them knowingly and purposefully. Abbott is thus not suggesting that the government should have mitigated damages that were suffered; instead, Abbott is arguing that the government caused the very injury that Ven-A-Care now alleges in its complaint. *See Fleet Nat. Bank v. Anchor Media Television, Inc.* 45 F.3d 546, 561 (1st Cir. 1995) (where the "question [is] whether the damages [plaintiff seeks] were caused by the conduct of which [it] complain[s]," the "doctrine of mitigation of damages is completely inapposite"). Indeed, Abbott is not faulting the government, as Ven-A-Care claims (Resp. at 18); the government maintained the spreads for justifiable reasons (*see* Abbott's SOAF to VAC's MSJ ¶¶ 84-96.) Abbott is simply saying (and the law supports) that Abbott should not now have to pay for the government's choice.

Ven-A-Care raises several other, equally meritless arguments in its Rule 56.1 response. Because decades of documents together show that the government knew about and purposefully used the alleged spreads, it does not matter that a single document standing on its own does not "indicate approval by the United States." Ven-A-Care's assertion also misstates the standard;

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[7] Nor is Abbott claiming that the government was too slow to change the Medicaid payment system (VAC Resp. at 20). Accordingly, *Blue Cross Blue Shield of Mass. v. AstraZeneca Pharms. LLP*, C.A. No. 08-1056, 2009 U.S. App. LEXIS 20977 (1st Cir. Sept. 23, 2009), does not apply.

formal approval is not necessary to disrupt causation. Ven-A-Care's complaint that some documents are from the 1980s and early 1990s – the odd argument that the government knew too much too early – is legally unsupported and factually nonsensical, particularly in the absence of any indication that spreads disappeared between the early 1990s and 2001. Similarly, while not every document mentions Abbott or Ery drugs by name, many do, and it is the cumulative knowledge shown by all of the documents that must be considered by the Court.[8] Finally, it does not matter whether or not a report counts as a public disclosure under the FCA's public disclosure bar (and in fact the cited documents do); the document is still relevant to the causation and damages issues raised in Abbott's motion for summary judgment.

While Abbott is confident that a jury will find no causation or damages at any time, the evidence is overwhelming and undisputed as of February 2001. Therefore, the Court should enter summary judgment finding that there can be no claim or damages after that date.

III. BECAUSE VEN-A-CARE HAS FAILED TO SHOW A VIOLATION OF THE ANTI-KICKBACK STATUTE, THE COURT SHOULD ENTER SUMMARY JUDGMENT FOR ABBOTT ON COUNT I.

Count I (Ven-A-Care's claim under 31 U.S.C. § 3729(a)(1)) fails because Ven-A-Care cannot establish a violation of the Anti-Kickback Statute, upon which the count is based. Ven-A-Care merely argues that it has satisfied this Court's *pleading* standard for an Anti-Kickback claim (VAC Resp. at 22) and that it "has set forth significant evidence to support its allegation that Abbott's pricing manipulation and concealment *caused the publication of inflated pricing* and that Abbott perpetrated this conduct *while aware* that such practices affected reimbursement spreads which pharmacies considered in purchasing generic drugs." (*Id.* 22-23 (emphasis added)

[8] *See United States v. Catholic Healthcare W.*, 445 F.3d 1147, 1152 (9th Cir. 2006) ("elements of the fraud allegation need not be made public in a single document"); *Dingle v. Bioport Corp.*, 388 F.3d 209, 214 (6th Cir. 2004) ("The fact that the information comes from different disclosures is irrelevant."); *United States ex rel. Reagan v. E. Tex. Med. Ctr. Reg'l Healthcare Sys.*, 384 F.3d 168, 174 n.8 (5th Cir. 2004) (multiple sources "considered as a whole").

(citing *In re Pharm. Industry Average Wholesale Price Litig.*, 491 F. Supp. 2d 12, 24-25 (D. Mass. 2007)).) This is not enough to avoid summary judgment.

This Court has ruled that the "mere publication of a false AWP, without more, does not constitute an offer of remuneration," and has noted that the Anti-Kickback Statute claim would turn on the actual proof of "marketing the spreads." *In re Pharm. Industry Average Wholesale Price Litig.*, 491 F. Supp. 2d at 18-19. An allegation of an "awareness" of the "potential" to market the spreads is insufficient to prove the required "offer" or "payment" of "remuneration."

Here, Ven-A-Care offers *no* proof that Abbott marketed the spreads on its Ery products. Ven-A-Care does not and cannot dispute that every Abbott PPD employee deposed on this issue testified that they thought that Abbott was reporting the prices that the pricing compendia wanted (SOF ¶¶ 57, 62-64) and unequivocally denied marketing the spread or setting prices in order to do so. (SOF Reply ¶ 66.) Instead, with no evidence that Abbott "actively used the inflated spread[s]. . . as a marketing tool" (as it alleged in the complaint ¶ 59), Ven-A-Care argues that Abbott "created reimbursement spreads with knowledge of those spread's potential marketing impact." (VAC Resp. at 24.) Again, that is not enough. Ven-A-Care's allegation of an "awareness" of the "potential" to market the spreads is insufficient to prove an "offer" or "payment" of "remuneration" as required by the Anti-Kickback Statute. *See In re AWP*, 491 F. Supp. 2d at 24-25. Ven-A-Care's theory cannot survive a motion for summary judgment.[9] Ven-A-Care's assertion that Abbott "actively communicated or enabled the communication of

[9] Ven-A-Care's Response does not address Abbott's point that, where a FUL or MAC caps Medicaid payment (as with the Erys), there is no incentive for a manufacturer to raise AWPs or for a pharmacy to purchase a drug with a higher AWP and that, accordingly, Ven-A-Care's theory of remuneration makes no sense. Indeed, Ven-A-Care presents no evidence that Abbott's spreads were larger than any competitor's, that any provider dispensed and submitted a claim for an Abbott Ery instead of a competing product, or that Abbott's pricing or reporting affected Abbott's market share. The Court previously recognized this problem with Ven-A-Care's allegations. *See In re Pharm. Industry Average Wholesale Price Litig.*, 491 F. Supp. 2d at 24-25 ("[Abbott] has the better argument that mere publication of a false AWP, without more, does not constitute an offer of remuneration where reimbursement is based on a median of AWPs, as it is with Abbott's multi-source drugs.").

reimbursement information" has been indisputably disproved (SOF Reply ¶ 66), and would not suffice on its own to prove a violation of the Anti-Kickback Statute even if true.

IV. THE COURT SHOULD ENTER SUMMARY JUDGMENT ON THE TEXAS AND CALIFORNIA CLAIMS, WHICH VEN-A-CARE HAS ALREADY SETTLED.

In the agreements and releases to settle the lawsuits that VAC filed in Texas and California, Ven-A-Care expressly agreed "not to sue or take any other civil or administrative action against Abbott based on the Covered Conduct," which the parties agree covers the Ery claims for Texas and California in this case. (SOF Reply ¶¶ 130-32.) Having released these claims and agreed not to sue, Ven-A-Care cannot include the Texas and California claims in this case.

Ven-A-Care's argument that the express covenant not to sue "only covers future suits" is preposterous. The Settlement Agreements most certainly do not say that. As a last gasp, Ven-A-Care suggests that the Settlement Agreements "expressly preserved" these claims, but that is not true. This case involving the Erys is referenced in the Settlement Agreements only to limit *Abbott's* release of Ven-A-Care and to preserve *Abbott's* rights. (Berlin Ex. 107 ¶ 6.) It specifically was not in the paragraph limiting Ven-A-Care's release of claims. Similarly, Ven-A-Care cannot get around the covenant not to sue by arguing that the covenant should not apply here where the government's interest is at stake. The Settlement Agreements clearly envisioned Ven-A-Care's role as an FCA relator and clearly stated that Ven-A-Care would not sue. Holding that the covenant does not apply where Ven-A-Care sues as a relator would eviscerate the agreement and would be unprecedented. The Court should enter summary judgment on the Texas and California claims.

V. THERE CAN BE NO DAMAGES FOR MEDICAID PAYMENTS NOT BASED ON A REPORTED ERY PRICE OR DAMAGES DERIVED FROM DR. DUGGAN'S FLAWED EXTRAPOLATIONS.

A. Ven-A-Care Cannot Collect Damages For Medicaid Payments That Were Not Based On A Price Reported For An Abbott Ery Product.

Ven-A-Care does not dispute that the reported prices about which it complains did not cause the Medicaid payments at issue. (*See* Abt. Br. at 27-31; VAC Resp. at 3.) Ven-A-Care has no evidence concerning if or how Abbott's allegedly inflated prices impacted the MAC and FUL levels set by the states and federal government. (SOF ¶¶ 67-77; 87-92.) Instead, Ven-A-Care resurrects an argument that this Court has already rejected: had Abbott reported lower prices, those lower prices would have led to lower Medicaid payments in certain states. (VAC Resp. at 24-25.) This argument cannot stand in view of this Court's ruling. *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 478 F.Supp. 2d at 180. Indeed the entire premise of Ven-A-Care's case – that Abbott reported allegedly inflated prices in order to provide a kick-back to its customers and increase its market share (*see* SOF ¶ 21) – collapses when a state does not base reimbursement on the reported price, such as when a state sets a MAC or the federal government sets a FUL. Under that frequent scenario, Abbott could not increase its market share by manipulating reported prices. Consistent with its prior orders, the Court should not allow recovery of damages for any claims paid based on something other than a compendia-reported price. *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 478 F.Supp. 2d at 180.[10] Compounding

[10]Ven-A-Care's attempt to distinguish this Court's ruling fails. It is based on the demonstratively incorrect and immaterial assertion that California MAC prices were usually higher than FULs for the Ery drugs. The record evidence shows that California established MACs for several Ery products that were lower than the FULs. Ven-A-Care then tries to preserve its damages claim by turning to the FULs, but the record indicates that the FULs were not used for the Ery payments and that the FULs were not based on reported Ery prices anyway. Unlike the defendants in the California case, in light of the testimony of CMS representatives, Abbott does not concede that its WAC had an impact on the FUL prices. (SOF ¶¶ 73-78.) Only when the reporting of a true AWP would have "shifted" or lowered the amount paid for the FUL can Abbott be the legal cause of the injury. *In Re AWP*, 491 F.Supp.2d at 99. Because CMS exercised discretion and did not uniformly choose the least costly therapeutic equivalent, there is no proof that the FUL would have been lower had Abbott reported a lower price. (SOF ¶¶ 73-78.)

its errors, Ven-A-Care failed to determine if other factors, including other companies' inflated reporting, led to higher MACs or FULs, thereby impermissibly inflating Ven-A-Care's damages from its simplistic subtraction formula.

B. No Damages Derived From Dr. Duggan's Flawed and Inadmissible Extrapolations.

Ven-a-Care defensively asserts that its expert had only a "few extrapolations" for "a small minority" of claims and mostly from overlapping data, but that is not true. Duggan only used actual claims data for his computations for 15 of the 49 states. The fifteen states' claims data were not even complete, causing Duggan to use the data he had to "fill in the gaps." (*See* Exhibit A to Motion in Limine, Docket # 6443.) Duggan used this incomplete data set, a non-random sample, to manufacturer a "difference" figure for 34 states where he did not rely upon any actual claims data. (SOF ¶¶ 105, 108.) Duggan's methods are contrary to the standard, traditional, method of compiling a random sample, *i.e*. a sample of representative claims from all Medicaid states. (SOF ¶ 121.) Duggan's extrapolation likewise erroneously assumed that the impact of his "but-for" prices on Medicaid spending would be the same for claims paid for the 34 no-data states as it was for the 15 states in his non-random sample. Duggan's failure to consider the nuances of each states' reimbursement policies, including the operation of state MACs, resulted in scenarios in which pharmacists would have received absurdly low, unacceptable, reimbursement payments. (SOF ¶¶ 118, 127.) Duggan's oversight and failure to account for the variability in payments bases renders his extrapolations unreliable and overstated. Thus, this Court can have no confidence in his results, and should enter judgment for Abbott on the damages claims based on Duggan's extrapolations.

CONCLUSION

For the reasons stated above and its Abbott's opening brief, this Court should grant Abbott's motion and enter summary judgment for Abbott on the claims raised in Abbott's motion.

Dated: December 4, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Tara A. Fumerton, an attorney, hereby certify that I caused a true and correct copy of the foregoing ABBOTT LABORATORIES INC.'S REPLY IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 4th day of December, 2009.

/s/ Tara A. Fumerton
Tara A. Fumerton